POWER2DM

"Predictive model-based decision support for diabetes patient empowerment"

Research and Innovation Project
PHC 28 – 2015: Self-management of health and disease and decision support systems based on predictive computer modelling used by the patient him or herself

Deliverable 4.3

D4.2.1 Sensor Integrators

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EXECUTIVE SUMMARY

This deliverable describes the choice of the sensors to be used within POWER2DM.

In addition, it provides a definition and a design of the APIs that will be used for data extraction from these sensors to the eHhealth platform (i.e., the Power2DM Personal Data Store).

POWER2DM Consortium Partners

Abbv	Participant Organization Name	Country
TNO	Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek	Netherlands
IDK	Institute of Diabetes “Gerhardt Katsch” Karlsburg	Germany
SRDC	SRDC Yazilim Arastirma ve Gelistirme ve Danismanlik Ticaret Limited Sirketi	Turkey
LUMC	Leiden University Medical Center	Netherlands
SAS	SAS Servicio Andaluz de Salud	Spain
SRFG	Salzburg Research Forschungs Gesellschaft	Austria
PD	PrimeData	Netherlands
iHealth	iHealthLabs Europe	France

OPEN ISSUES

No:	Date	Issue	Resolved
1	26th April	Full implementation of APIs extracting data from sensors has yet to be finalized.	
2	August 31	Cloud-to-cloud integration of FSL data not possible in short future	

TABLE OF CONTENTS

1 INTRODUCTION

1.1 Purpose and Scope

This document describes the choice of the sensors to be used within POWER2DM as well as the definition, design and development of the corresponding APIs for data extraction to the Ehealth platform.

1.2 References to POWER2DM Documents

- POWER2DM Description of Work (Proposal)
- D1.3
- D2.1
- D2.2
- D5.2

1.3 Definitions, Abbreviations and Acronyms

Table 1 List of Abbreviations and Acronyms

Abbreviation/ Acronym	DEFINITION
API	Application Programming Interface
ARC	Audit Repository Client component
ATNA	IHE Audit Trail and Node Authentication Profile
CGM	Continuous Glucose Monitoring
EC	Evaluation Campaign
ETL	Extract, Transform, Load operations
FHIR	HL7 Fast Healthcare Interoperability Resources Standard
FSL	Abbott FreeStyleLibre Flash Glucose Monitoring system
PDS	POWER2DM Personal Data Store component
REST	Restful Service
UI	User interface
QC	Quantification Campaign

2 CHOICE OF SENSORS

2.1 Sensor requirements

As described in the POWER2DM Workplan (p.22), WP4 will provide, amongst others, the necessary sensor integrations to collect the listed data from different data sources in real-time. The aim is to use technological developments and existing systems in the area of self-monitoring, wearables, sensors and devices to achieve unobtrusive sensing while maintaining the reliability and accuracy of data.

The selection of sensors to be used within the project is largely determined by the data requirements of the predictive models. Principally, the sensors aim at grounding and calibrating these models with experimental data and finetuning the developed computational patient models and clinical state prediction frameworks. In this early phase of the project we aim to define a minimal set of sensors that together offer maximal data relevant for POWER2DM's predictive models and for selfmanagement. We also aim for devicesfrom which data can be extracted already dring the Quantification Campaign.

First of all, patients are asked to undertake (semi) continuous blood glucose monitoring over a period of maximally one month in order to asses glycemic control. Series of blood glucose levels belong to the primary input measures used in the KADIS model and will be used as the outcome for assessing the use of this model and whether the simulations can be used for glucose prediction.

In addition, sensors are needed to help patients in recording their daily food intake, monitoring their daily exercise levels and sleep quality, recording their daily diabetes treatments, and tracking their heart rate. All this data will be used to ground and calibrate the type 1 and type 2 diabetes patient fingerprint service (KADIS) and the prediction frameworks (KADIS,MT2D-Marvel and Risk Score models) of WP2.

Another goal of using a set of sensors is that of boosting the development of such personal devices that can be used for self-management of health (p.30).

The POWER2DM services enabling the retrieval of personalized predictions, simulations and corresponding advices should encourage patients to collect more data about themselves in order to get more and accurate results. This will boost the usage of medical devices among diabetes patients and stimulate sales of existing sensor devices. In addition, it will stimulate development of existing and new mobile devices that are even better suited for diabetes patients, for instance because of an increase in user-friendliness. Thus, the selection of adequate sensors will, in the end, create a solid basis for patient empowerment.

2.2 Selected sensors

To minimize the burden on diabetes patients, the amount of sensor devices used to collect data required by the POWER2DM services should be limited. We are thus looking for multi-functional devices that can serve multiple goals.

As indicated in the previous section, maintaining healthy blood glucose levels is the primary goal of all diabetes care and monitoring these levels is the basis for guiding actions to maintain these levels and prevent both short-term and long-term complications.

There exist a wide range of glucose self-monitoring sensors. These broadly classify into fingerprick glucometers, and devices for Continuous glucose monitoring (CGM). Fingerprick glucometers include e.g.:

Roche Accu-Chek (various models)

Acsensia Contour (various models)

Sanofi Aventis BG Star

Abbott Freestyle Lite/Insulinx

Sanofi Aventis IBG Star

iHealth Align Glucose meter (various models)

iHealth Smart wireless gluco-monitoring system

My Life Unio (Ypsomed)

Manufactures are continuously extendeding this list with new models.

Logically, since iHealth is partner in POWER2DM, the project will use the **iHealth Align glucose meter** for fingerprick glucose measurements. About the size of a quarter, this portable glucometer fits easily into a pocket and attaches directly to a smartphone or tablet via the headphone jack for fast, accurate readings whenever, wherever. This portable glucometer works with the free Gluco-Smart app for iOS and Android devices to help patients manage their diabetes. Align allows one to measure and record blood sugar readings, and share measurements with the doctor right from a smartphone or tablet. The meter is used with iHealth test strips.

Also a range of CGM glucometers is available. These often form part of a system that also includes an insulin pump. Availability of sensors may differ per country.

Examples of real-time CGM sensors/systems include e.g.:

Medtronic Enlite/Minimed/Guardian

Dexcom G4/G5

Abbott Freestyle Navigator

An increasingly widely accepted sensor device that can be used to measure interstitial fluid glucose levels with limited burden to the patient, and reduced costs compared to true real-time CGM sensors, is the **FreeStyle Libre (FSL) Flash Glucose Monitoring System** which will be used in POWER2DM. This is not a true continuous sensor, since it measures glucose intermittently however with a high time resolution, resulting in a quasi-continuous glucose time curve. This is therefore called Flash Glucose Monitoring. The FSL system consists of a small FSL Sensor and a wireless FSL Reader. The FSL Sensor allows for 8 hours of continuous measurement and storing of interstitial fluid glucose levels. Each sensor is valid for a period of two weeks and can be installed by the patient. The stored information

can be retrieved using either the FSL Reader or with an NFC enabled Android device. When either the FSL Reader or NFC enabled Android device are held over the FSL Sensor they retrieve the previous eight hours of blood glucose level data wirelessly. The FSL has been tested and found to be at least 85.2% accurate over a 14 day period. The FSL Reader will also be used for the 8/day blood glucose checks using fingerpricks during the first 72 hours and all subsequent blood glucose checks. Patients will perform the finger-pricks at least twice a day (morning and evening) or as frequently as they do in their current diabetes treatment plan, whichever is more. In the QC, the patients will perform FGM during weeks 1-4 and weeks 11-12. All glucose readings will be uploaded to the patient's profile in PatientCoach over the internet either automatically as is the case with the FSL with NFC connected devices or through manual uploading the collected data as is the case with the FSL Reader.

Both the KADIS and the MT2D-Marvel prediction service require information on a patient's exercise levels. In addition, the MT2D-Marvel model also needs explicit knowledge about periods of non-activity, that is: information regarding duration, frequency and quality of sleep.

The **Fitbit HR Charge** is a wristband activity tracker that counts steps, tracks physical activity and sleep, allows for monitoring of pulse rate and tracks calorie burn. It has a non-intrusive design, can automatically upload tracked information to connected devices, and can easily integrate with MyFitnessPal. Further, the five day battery life reduces the burden of maintenance for the patients as they will not need to load the battery every day. Also, Fitbit HR Charge is already integrated into PatientCoach which is the eHealth application for clinical research settings used in the Quantification Campaign.

Additionally, the Fitbit HR Charge can be used to measure sleep duration, frequency, and quality/disturbances. The Fitbit HR Charge automatically begins to track sleep based on user movement thus decreasing the risk that the patients will forget to turn on their sleep tracker.

The MT2D-Marvel prediction model requires input data for the parameters stress,relaxation and sleep quality. Scores for these parameters can be derived from information on heart rate and respiratory rate.

The **FitbitHR Charge** measures relaxation as a product of resting heart rate and inactivity. Additionally, the **Spire** can be used to measure respiratory rate. The Spire is a small eHealth device that is clipped on to the waistband of a participant and records continuous measurements of inhalation and exhalation times, breath rate, deep breaths, apnoeic events. It analyses breathing patterns to infer state of mind (tense, calm, focus) and has been validated as a reliable and non-invasive index of emotion regulation abilities in times of stress.

In sum, then, all self-monitoring data required by the POWER2DM predictive models in the Pilot Studies will be collected by means of four devices: **FreeStyle Libre** Flash Glucose Monitoring, **iHealth Align** fingerprick glucometer, **Fitbit HR Charge** Activity, Heart Rate and Sleep tracker, and **Spire** Respiratory rate tracker.

3 SENSOR DATA COLLECTION

3.1 Sensor Data Retrieval

Data collected by the selected sensor devices – FreeStyle Libre, FitbitHR Charge and Spire – will be collected in two ways. For two of them – Fitbit HR Charge and Spire – Application Programming Interfaces (APIs) have been developed. These APIs will be addressed in order to get the right data needed for running the POWER2DM services. Data collected by the FreeStyle Libre will be uploaded, either automatically or manually, to the PDS. Data collected by the iHealth Align glucometer will be transferred to POWER2DM from the iHealth Cloud. Below we provide a short summary of the respective data retrieval methods.

3.1.1 Fitbit HR Charge (https://dev.fitbit.com/docs/)

Fitbit provides a Web API for accessing data from Fitbit activity trackers, such as the Fitbit HR Charge. All requests to the Fitbit Web API must use HTTPS. To use the Fitbit Web API, one's application should first be registered.

The Fitbit Web API uses the OAuth 2.0 protocol for user authorization. The OAuth 2.0 framework requires an application to obtain an Access Token when a Fitbit user authorizes that application to access their data. The Access Token is used for making HTTP request to the Fitbit API.

The Fitbit Web API can be addressed to retrieve activity data, body weight data, heart rate data and sleep data.

The *Get Daily Activity Summary* endpoint retrieves a summary and list of a user's activities and activity log entries for a given day in the format requested using units in the unit system which corresponds to the Accept-Language header provided. The *Get Activity Time Series* endpoint returns time series data in the specified range for a given resource in the format requested using units in the unit system that corresponds to the Accept-Language header provided.

The *Get Body Fat Logs* API retrieves a list of all user's body fat log entries for a given day in the format requested. Body fat log entries are available only to authorized user. If you need to fetch only the most recent entry, you can use the *Get Body Measurements* endpoint. The *Get Body Time Series* API returns time series data in the specified range for a given resource in the format requested using units in the unit system that corresponds to the Accept-Language header provided.

The *Get Heart Rate Time Series* endpoint returns time series data in the specified range for a given resource in the format requested using units in the unit system that corresponds to the Accept-Language header provided.

The *Get Sleep Logs by Date* endpoint returns a summary and list of a user's sleep log entries (including naps) as well as detailed sleep entry data for a given day. This endpoint supports two kinds of sleep data:

- stages: Levels data is returned with 30-second granularity. 'Sleep Stages' levels include 'deep', 'light', 'rem', and 'wake'.

- classic: Levels data returned with 60-second granularity. 'Sleep Pattern' levels include ‘asleep’, ‘restless’, and ‘awake’.

The response could be a mix of classic and stages sleep logs.

3.1.2 Spire (http://developer.spire.io/docs)

The Spire API is not publicly accessible (http://support.spire.io/customer/en/portal/topics/905979-developers-api/articles). To retrieve access to it, a request should be sent to Spire itself.

Only after having obtained an access token can one make use of the endpoints available in the Spire API.

The *streaks* endpoint returns a list of a user’s streaks. This includes information on the streak type ("calm", "focus", "tense", "activity", "sedentary", "disconnected", "charging", "not_worn" or "neutral") and on the streak period. In case of ‘activity’ streak, additional information is given about the number of steps taken and the amount of calories burned. In case of ‘calm’, ‘focus’, ‘tense’ and ‘sedentary’ streaks, one is provided with the average breath rate. Finally, if the streak type has been edited by the user, the original streak type is given, too.

The *events* endpoint returns a list of events for a specified date and type of event (‘br’ = breath rate in breaths per second, ‘steps’ = number of steps taken, ‘calories’ = number of calories burned). The response includes, respectively, the breath rate, the number of steps taken or the number of calories burned on the given date.

3.1.3 FreeStyle Libre

Two options exist:

- Upload (automatically or manually) to a specific service (PatientCoach or PDS)
- Use Night-scout set-up
    - The FSL data in the QC is currently manually uploaded by the patient/researcher after downloading the data file from the reader over a physical connection (the LibreLink and LibreLinkUP apps do not have an open API; it is possible to do this automatically via a night scout (** N.B. this is not officially supported but highly desired by patients; it requires an Android device with NFC**). So at present there is no data collection process other than uploading of CSV files.

3.1.4 iHealth Align

For this device, partner iHealth will provide the cloud-to-cloud integration to the POWER2DM PDS based on the PDS resources for glucose measurements. This is not further described in Ch. 4.

3.2 Storage of sensor data in POWER2DM Personal Data Store

The Personal Data Store (PDS) securely stores any personal health data collected or generated within POWER2DM Care Program for patients. It provides software interfaces for other POWER2DM components and UIs to securely access on behalf of an authorized user or for their internal data processing/algorithmic needs. HL7 Fast Healthcare Interoperability Resources (FHIR) DSTU 22 is selected as the base standard for the common personal health data exchange model for POWER2DM.
The PDS will also be used to store personal data and contextual data like location (home, office, etc.), interruptibility, activity (walking, transportation, etc.) that can be derived from the on-board mobile phone sensors. For such records, data will be stored in its raw format and be accessible to only POWER2DM system for internal processing through the PDS's Analytics/ETL endpoint.

4 IMPLEMENTATION

4.1 Sensor Data Retrieval and Storage in the POWER2DM Personal Data Store

In this section, we describe our implementation of the workflow involving the retrieval of data from the sensor devices and the storage of these data into the POWER2DM Personal Data Store.

4.1.1 FitBit HR Charge

In the first prototype, Fitbit is used for retrieving sleep data and heart rate data. For both types of data TNO has developed an API service that will have to be called daily by an application regulating the retrieval of Power2DM Sensor data. Such an application has been implemented by PrimeData. The application has to send a Power2DM patient-id and a date to the API services. As a response it will receive either an id under which the Fitbit data requested has been stored in the PDS or a warning indicating no Fitbit data was available for the given patient at the given date (for example because the patient forgot to synchronize the Fitbit device).

Both API services have been incorporated in TNO's Life Sciences Platform DIAMONDS. Communication with these APIs takes place via a so-called JWT protocol: clients have to authenticate by sending their DIAMONDS credentials. After successful authentication, clients will receive a JSON Web Token that should be passed in subsequent calls to the DIAMONDS API services in order to obtain access to them.

Below we describe what the DIAMONDS Fitbit services actually do.

4.1.1.1 Fitbit Sleep Data in PDS

In addition to an authentication token that has to be provided in the request header, the API service 'Store_FitbitSleepData_in_PDS' requires two inputs: a Power2DM patient ID and a date.

These inputs are passed to a PHP script which first maps the patient ID to a Fitbit account.[1] Subsequently, it uses the refreshToken stored for this Fitbit account to retrieve a new accessToken via the OAuth2 protocol that needs to be used when addressing the Fitbit services.

Then, the accessToken and the date passed to the PHP script are sent to Fitbit's *Get Sleep Logs by Date* endpoint (see section 3.1.1). If any data is available for the given account at the specified date, the following output is received by the PHP script: start time of sleep period, end time of sleep period, duration of sleep period (in minutes), time before falling asleep (in minutes), sleep efficiency score, number of awake periods interrupting the sleep period, and the number of restless times interrupting the sleep period.

These outputs are taken from the PHP script and then passed to an R script translating them to a FHIR format that can easily be imported in the PDS.

Finally, the PDS is addressed by an API requestor sending the sleep data retrieved from Fitbit for being stored.

If the patient ID could not be mapped to a Fitbit account or no sleep data was available for the given date, the API service returns a warning informing the client about this. Otherwise, both the retrieved Fitbit data and the id under which they have been stored in the PDS will be returned.

The whole process is schematically presented in Figure 1.

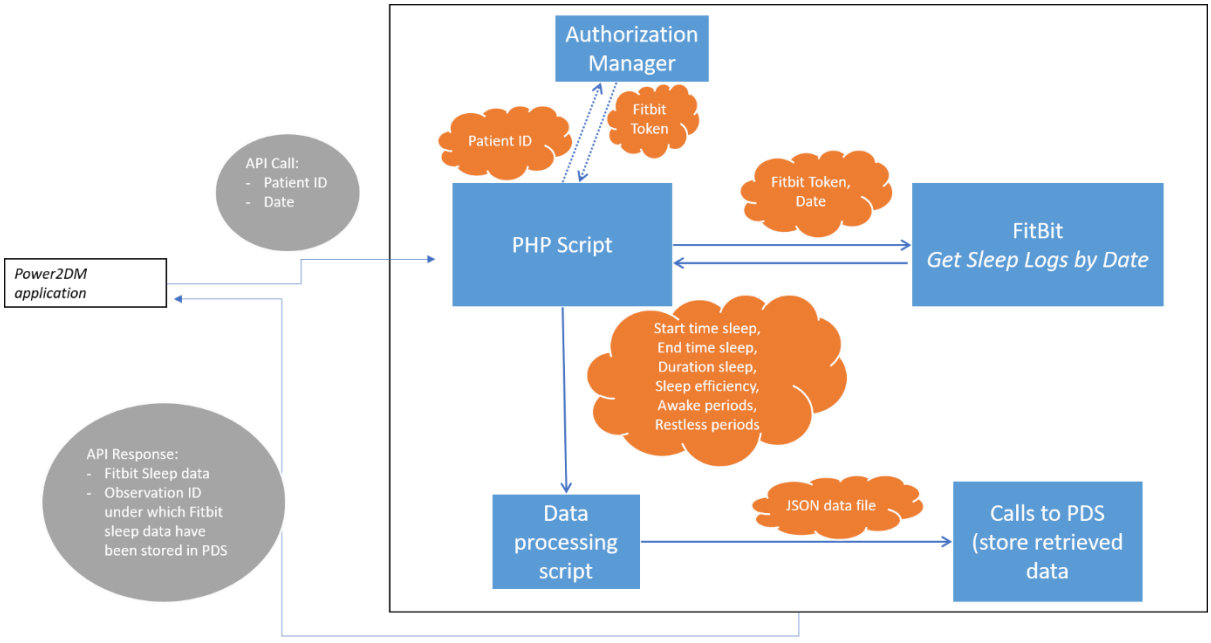

Figure 1 - Schematic representation of the Store Fitbit Sleep Data Service

[1] This mapping is going to be retrieved from the Authorization Manager.

4.1.1.2 Fitbit HeartRate Data in PDS

The API service 'Store_FitbitHeartRateSummaryData_in_PDS' requires the same two inputs: a Power2DM patient ID and a date.

These inputs are passed to a PHP script which, after mapping the patient ID to a Fitbit account and getting a valid accessToken for that account, sends the date (together with the accessToken) to Fitbit's *Get Heart Rate Time Series* endpoint (see section 3.1.1). If any data is available for the given account at the specified date, the following output is received by the PHP script:

- an average resting heart rate
- for each of the four possible 'heart rate zones' ('out of zone' (= very low), 'fat burn', 'cardio' and 'peak'):
    - the minimum heart rate
    - the maximum heart rate
    - the total duration of all periods having this heart rate zone during the day
    - the total amount of calories burnt during these periods

These outputs are taken from the PHP script and then passed to an R script translating them to a FHIR format that can easily be imported in the PDS.

Finally, the PDS is addressed by an API requestor sending the heartrate data retrieved from Fitbit for being stored.

If the patient ID could not be mapped to a Fitbit account or no heartrate data was available for the given date, the API service returns a warning informing the client about this. Otherwise, both the retrieved Fitbit data and the id under which they have been stored in the PDS will be returned.

The whole process is schematically presented in Figure 2.

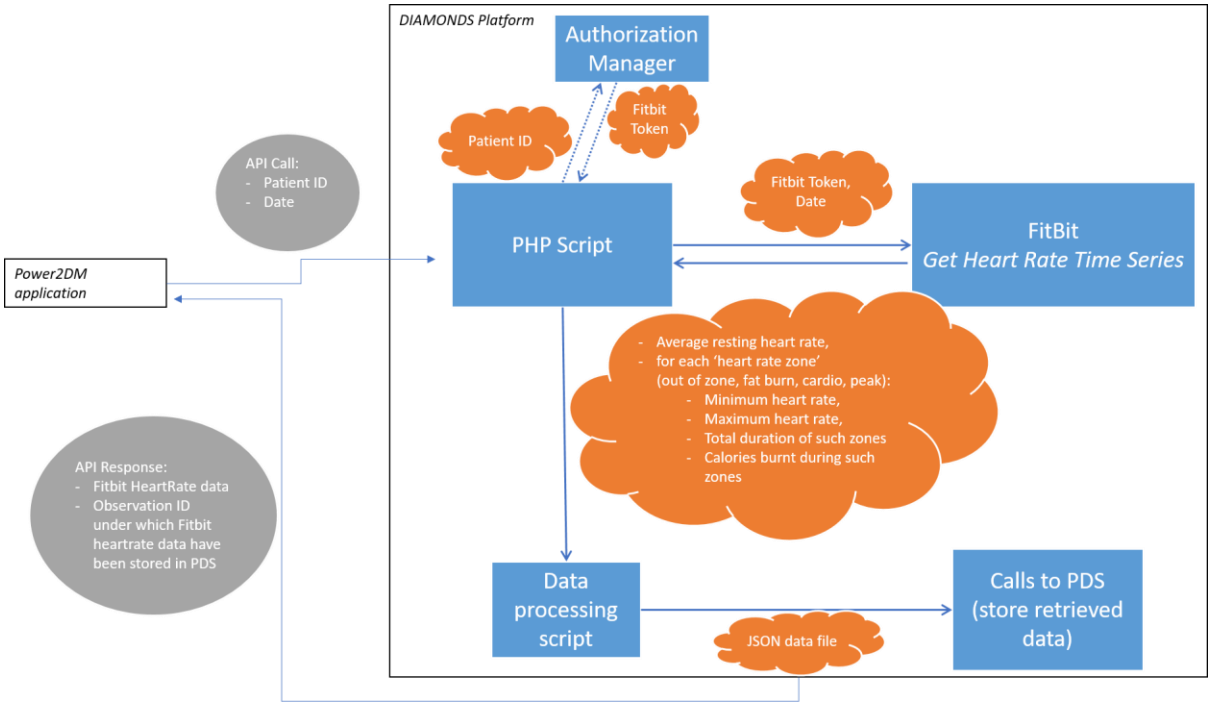

Figure 2 - Schematic representation of the Store Fitbit HeartRate Data Service

4.1.2 Spire

For Spire, the same approach as for Fitbit will be taken. Implementation of Spire data integration has previously been done by LUMCin their PatientCoach application that is also used in the QC. POWER2DM will make use of code from the at LUMC in case, based on QC results, it is decided to pursue using Spire.

4.1.3 FreeStyle Libre

Unfortunately, no cloud-to-cloud integration with the FSL supported by Abbott is possible at present.
In principle there is a possibility for cloud-to-cloud integration with the Diasend platform which also supports FSL data. Diasend has recently been acquired by Glooko. Contacts were established but at present the company gives priority to integrate the Diasend platform, and integration with other platforms such as POWER2DM is postponed for the time being.
Therefore, POWER2DM will integrate FSL data via a semi-automated procedure. The FSL reader can export a .csv file which will be imported by a POWER2DM service that converts the data to POWER2DM format and uploads it into the PDS.

5 LITERATURE

Deliverable 5.2 (Protocol for the Quantification Campaign) contains various references to relevant scientific literature re. sensors. These are not repeated in this deliverable.